

FORM PTO-1449  
U.S. Department of Commerce Patent and  
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INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

Docket No. SALK2270-1

Serial No. 09/227,718

Applicant(s): Ronald M. Evans

Filing Date: January 8, 1999

Group Art Unit: 1643

U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
JW	AA	4,160,152	07/03/79	Wightman et al.	219	438	12/04/78
J	AB	4,256,108	03/17/81	Theeuwes	128	260	05/21/79
J	AC	4,265,874	05/05/81	Bonsen et al.	424	15	04/25/80

FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATI <sup>N</sup> (YES/NO)
		NONE					

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

JW	AD	Adlercreutz and Mazur, "Phyto-oestrogens and Western Diseases," <i>Ann. Med.</i> , 29:95-120 (1997)
	AE	Altschul et al., "Basic Local Alignment Search Tool," <i>J Mol. Biol.</i> , 215:403-410 (1990)
	AF	Baes et al., "A New Orphan Member of the Nuclear Hormone Receptor Superfamily That Interacts with a Subset of Retinoic Acid Response Elements," <i>Molecular and Cellular Biology</i> , 14(3):1544-1552 (1994)
	AG	Bahouth et al., "Immunological approaches for probing receptor structure and function," <i>TIPS Reviews</i> , 12:338-343 (1991)
	AH	Bammel et al., "Divergent effects of different enzyme-inducing agents on endogenous and exogenous testosterone," 42:641-644 (1992)

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<i>JW</i>	AI	Barwick et al., "Trans-species Gene Transfer for Analysis of Glucocorticoid-Inducible Transcriptional Activation of Transiently Expressed Human CYP3A4 and Rabbit CYP3A6 in Primary Cultures of Adult Rat and Rabbit Hepatocytes," <i>Molecular Pharmacology</i> , 50:10-16 (1996)
	AJ	Beato et al., "Steroid Hormone Receptors: Many Actors in Search of a Plot," <i>Cell</i> , 83:851-857 (1995)
	AK	Beaune et al., "Isolation and sequence determination of a cDNA clone related to human cytochrome P-450 nifedipine oxidase," <i>Proc. Natl. Acad. Sci.</i> , 83:8064-8068 (1986)
	AL	Blumberg et al., "Novel retinoic acid receptor ligands in Xenopus embryos," <i>Proc. Natl. Acad. Sci.</i> , 93:4873-4878 (1996)
	AM	Blumberg et al., "BXR, an embryonic orphan nuclear receptor activated by a novel class of endogenous benzoate metabolites," <i>Genes &amp; Development</i> , 12:1269-1277 (1998)
	AN	Burger et al., "Paradoxical transcriptional activation of rat liver cytochrome P-450 3A1 by dexamethasone and the antiglucocorticoid pregnenolone 16 $\alpha$ -carbonitrile: Analysis by transient transfection into primary monolayer cultures of adult rat hepatocytes," <i>Proc. Natl. Acad. Sci. (USA)</i> , 89:2145-2149 (1992)
	AO	Denison and Whitlock, "Xenobiotic-inducible Transcription of Cytochrome P450 Genes," <i>Journal of Biological Chemistry</i> , 270(31):18175-18178 (1995)
	AP	Devereux et al., "A comprehensive set of sequence analysis programs for the VAX," <i>Nucleic Acids Research</i> , 12:387-395 (1984)
	AQ	Edwards et al., "Changes in Cortisol Metabolism Following Rifampicin Therapy," <i>The Lancet</i> , 2:549-551 (1974)
	AR	Elshourbagy and Guzelian, "Separation, Purification, and Characterization of a Novel Form of Hepatic Cytochrome P-450 from Rats Treated with Pregnenolone-16 $\alpha$ -carbonitrile," <i>Journal of Biological Chemistry</i> , 255:1279-1285 (1980)
	AS	Enmark and Gustafsson, "Orphan Nuclear Receptors - The First Eight Years," <i>Mol. Endo.</i> , 10(11):1293-1307 (1996)

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<i>JW</i>	AT	Evans, Ronald M., "The Steroid and Thyroid Hormone Receptor Superfamily," <i>Science</i> , <b>240</b> :889-895 (1988)
	AU	Fernandez-Salguero and Gonzalez, "The CYP2A gene subfamily: species differences, regulation, catalytic activities and role in chemical carcinogenesis," <i>Pharmacogenetics</i> , <b>5</b> :S123-S128 (1995)
	AV	Forman et al., "Unique Response Pathways Are Established by Allosteric Interactions among Nuclear Hormone Receptors," <i>Cell</i> , <b>81</b> :541-550 (1995)
	AW	Forman et al., "Hypolipidemic drugs, polyunsaturated fatty acids, and eicosanoids are ligands for peroxisome proliferator-activated receptors $\alpha$ and $\delta$ ," <i>Proc. Natl. Acad. Sci. USA</i> , <b>94</b> :4312-4317 (1997)
	AX	Gonzalez et al., "Complete cDNA and Protein Sequence of a Pregnenolone 16 $\alpha$ -Carbonitrile-induced Cytochrome P-450," <i>Journal of Biological Chemistry</i> , <b>260</b> (12):7435-7441 (1985)
	AY	Gonzalez et al., "Pregnenolone 16 $\alpha$ -Carbonitrile-Inducible P-450 Gene Family: Gene Conversion and Differential Regulation," <i>Molecular and Cellular Biology</i> , <b>6</b> (8):2969-2976 (1986)
	AZ	Gonzalez, Frank J., "Human cytochromes P450: problems and prospects," <i>TIPS Reviews</i> , <b>13</b> :346-352 (1992)
	BA	Gottlicher et al., "Fatty acids activate a chimera of the clofibrate acid-activated receptor and the glucocorticoid receptor," <i>Proc. Natl. Acad. Sci. USA</i> , <b>89</b> :4653-4657 (1992)
	BB	Guengerich, F. Peter, "Metabolism of 17 $\alpha$ Ethyneestradiol in Humans", <i>Life Sciences</i> , <b>47</b> :1981-1988 (1990)
	BC	Hankinson, Oliver, "The Aryl Hydrocarbon Receptor Complex," <i>Annu. Rev. Pharmacol. Toxicol.</i> <b>35</b> :307-340 (1995)
	BD	Hardwick et al., "Cloning of DNA Complementary to Cytochrome P-450 Induced by Pregnenolone-16 $\alpha$ carbonitrile," <i>Journal of Biological Chemistry</i> , <b>258</b> :10182-10186 (1983)

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9W	BE	Henikoff and Henikoff, "Amino acid substitution matrices from protein blocks," <i>Proc. Natl. Acad. Sci. USA</i> , 89:10915-10919 (1992)
	BF	Heuman et al., "Immunochemical Evidence for Induction of a Common Form of Hepatic Cytochrome P-450 in Rats Treated with Pregnenolone-16 $\alpha$ -carbonitrile or other Steroidal or Non-Steroidal Agents," <i>Molecular Pharmacology</i> , 21:753-760 (1982)
	BG	Hollenberg et al., "Primary structure and expression of a functional human glucocorticoid receptor cDNA," <i>Nature</i> , 318(6047):635-641 (1985)
	BH	Hollenberg et al., "Colocalization of DNA-Binding and Transcriptional Activation Functions in the Human Glucocorticoid Receptor," <i>Cell</i> , 49:39-46 (1987)
	BI	Holtbecker et al., "The Nifedipine-Rifampin Interaction: Evidence for Induction of Gut Wall Metabolism," <i>Drug Metabolism and Disposition</i> , 23(10):1121-1123 (1996)
	BJ	Jonat et al., "Antitumor Promotion and Antiinflammation: Down-Modulation of AP-1 (Fos/Jun) Activity by Glucocorticoid Hormone," <i>Cell</i> , 62:1189-1204 (1990)
	BK	Juchau, M.R., "Substrate Specificities and Functions of the P450 Cytochromes," <i>Life Sciences</i> , 47:2385-2394 (1990)
	BL	Kliewer et al., "Fatty acids and eicosanoids regulate gene expression through direct interactions with peroxisome proliferator-activated receptors $\alpha$ and $\gamma$ ," <i>Proc. Natl. Acad. Sci. USA</i> , 94:4318-4323 (1997)
	BM	Kliewer et al., "An Orphan Nuclear Receptor Activated by Pregnanes Defines a novel Steroid Signaling Pathway," <i>Cell</i> , 92:73-82 (1998)
	BN	Kolars et al., "First-pass metabolism of cyclosporin by the gut," <i>Lancet</i> , 338:1488-1490 (1991)
	BO	Kolars et al., "Identification of Rifampin-inducible P450llIA4 (CYP3A4) in Human Small Bowel Enterocytes," <i>Journal of Clinical Investigation, Inc.</i> , 90:1871-1878 (1992)
	BP	Kyriazopoulou et al., "Rifampicin-Induced Adrenal Crisis In Addisonian Patients Receiving Corticosteroid Replacement Therapy," <i>Journal of Clinical Endocrinology and Metabolism</i> , 59(6):1204-1206 (1984)

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<i>QW</i>	BQ	Kyriazopoulou and Vagenakis, "Abnormal Overnight Dexamethasone Suppression Test in Subjects Receiving Rifampicin Therapy," <i>Journal of Clinical Endocrinology and Metabolism</i> , 74(1):315-317 (1992)
	BR	Ladias and Karathanasis, "Regulation of the Apolipoprotein AI Gene by ARP-1 a Novel Member of the Steroid Receptor Superfamily," <i>Science</i> , 251:561-565 (1991)
	BS	Lee et al., "Time course of the changes in prednisolone pharmacokinetics after co-administration or discontinuation of rifampin," <i>Eur. Journal of Clinical Pharmacology</i> , 45:287-289 (1993)
	BT	Li and Evans, "Ligation independent cloning irrespective of restriction site compatibility," <i>Nucleic Acids Research</i> , 25:4165-4166 (1997)
	BU	Lonning et al., "Plasma Levels of Estradiol, Estrone, Estrone Sulfate and Sex Hormone Binding Globulin in Patients Receiving Rifampicin," <i>J. Steroid Biochem.</i> , 33(4A):631-635 (1989)
	BV	Mangelsdorf et al., "The Nuclear Receptor Superfamily: The Second Decade," <i>Cell</i> , 83:835-839 (1995)
	BW	Mangelsdorf and Evans, "The RXR Heterodimers and Orphan Receptors," <i>Cell</i> , 83:841-850 (1995)
	BX	McAllister et al., "Rifampicin reduces effectiveness and bioavailability of prednisolone," <i>British Medical Journal</i> , 286:923-925 (1983)
	BY	Miyata et al., "Transcriptional Elements Directing a Liver-Specific Expression of P450/6 $\beta$ A (CYP3A2) Gene-Encoding Testosterone 6 $\beta$ -Hydroxylase," <i>Archives of Biochemistry and Biophysics</i> , 318(1):71-79 (1995)
	BZ	Molowa et al., "Complete cDNA sequence of a cytochrome P-450 inducible by glucocorticoids in human liver," <i>Proc. Natl. Acad. Sci. USA</i> , 83:5311-5315 (1986)
	CA	Nebert, Daniel W., "P450 Genes: Structure, Evolution, and Regulation," <i>Ann. Rev. Biochem.</i> , 56:945-993 (1987)

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*Joe Wunder*

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<i>QW</i>	CB	Needleman and Wunsoh, "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins," <i>Journal of Molecular Biology</i> , <b>48</b> :443-453 (1970)
	CC	O'Malley and Conneely, "Orphan Receptors: In Search of a Unifying Hypothesis for Activation," <i>Molecular Endocrinology</i> , <b>6</b> :1359-1361 (1992)
	CD	Ogura and Evans, "A retinoic acid-triggered cascade of HOXB1 gene activation," <i>Proc. Natl. Acad. Sci. USA</i> , <b>92</b> :387-391 (1995)
	CE	Ohnhaus et al., "Urinary Excretion of 6 $\beta$ -Hydroxycortisol and the Time Course Measurement of Enzyme Induction in Man," <i>Eur. J. Clin. Pharmacol.</i> , <b>36</b> :39-46 (1989)
	CF	Quattrochi et al., "A Novel cis-Acting Element in a Liver Cytochrome P450 3A Gene Confers Synergistic Induction by Glucocorticoids plus Antiglucocorticoids," <i>Journal of Biological Chemistry</i> , <b>270</b> (48):28917-28923 (1995)
	CG	Russel and Wilson, "Steroid 5 $\alpha$ -Reductase: Two Genes/Two Enzymes," <i>Annu. Rev. Biochem.</i> , <b>63</b> :25-61 (1994)
	CH	Schuetz and Guzelian, "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver," <i>Journal of Biological Chemistry</i> , <b>259</b> (3):1999-2006 (1984)
	CI	Schuetz and Guzelian, "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver," <i>Journal of Biological Chemistry</i> , <b>259</b> (3):2007-2012 (1984)
	CJ	Schule et al., "Functional Antagonism between Oncoprotein c-Jun and the Glucocorticoid Receptor," <i>Cell</i> , <b>62</b> :1217-1226 (1990)
	CK	Selye, H., "Hormones and Resistance," <i>Journal of Pharmaceutical Sciences</i> , <b>60</b> (1):1-28 (1971)
	CL	Sucov et al., "Characterization of an autoregulated response element in the mouse retinoic acid receptor type $\beta$ gene," <i>Proc. Natl. Acad. Sci. USA</i> , <b>87</b> :5392-5396 (1990)
	CM	Staden, Rodger, "The current status and portability of our sequence banding software," <i>Nucleic Acids Research</i> , <b>14</b> (1):217-231 (1986)

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<i>g6</i>	CN	Terzolo et al., "Misdiagnosis of Cushing's Syndrome in a Patient Receiving Rifampicin Therapy for Tuberculosis," <i>Horm. Metab. Res.</i> , 27:148-150 (1995)
	CO	Umesono et al., "Direct Repeats as Selective Response Elements for the Thyroid Hormone, Retinoic Acid, and Vitamin D <sub>3</sub> Receptors," <i>Cell</i> , 65:1255-1266 (1991)
	CP	Watkins et al., "Erythromycin Breath Test as an Assay of Glucocorticoid-inducible Liver Cytochromes P-450," <i>J. Clin. Invest.</i> , 83:688-697 (1989)
	CQ	Wietholtz et al., "Stimulation of bile acid 6α-hydroxylation by rifampin," <i>Journal of Hepatology</i> , 24:713-718 (1996)
	CR	Willy et al., "LXR, a nuclear receptor that defines a distinct retinoid response pathway," <i>Genes &amp; Development</i> , 9:1033-1045 (1995)
	CS	Wurtz et al., "A canonical structure for the ligand-binding domain of nuclear receptors," <i>Nature Structural Biology</i> , 3:87-94 1996)
	CT	Yang-Yen et al., "Transcriptional Interference between c-Jun and the Glucocorticoid Receptor: Mutual Inhibition of DNA Binding Due to Direct Protein-Protein Interaction," <i>Cell</i> , 62:1205-1215 (1990)
	CU	Zawawi et al., "The Effects of Therapy with Rifampicin and Isoniazid on Basic Investigations for Cushing's Syndrome," <i>Ir. J. Med. Sci.</i> , 165:300-302 (1996)

EXAMINER <i>Joe W. Dolan</i>	DATE CONSIDERED <i>6-10-00</i>
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